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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/731,224

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EXAMINER

TSAY, MARSHA M

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/731,224	Applicant(s) DESAI ET AL.	
	Examiner Marsha M. Tsay	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10.24.08</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1,4-18,84,97,98,100-108,110-117,119-128,130-132,134-137,139-141,143-218,220,221 and 224.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 4,15-18,102,108,110-117,119-127,143-147,149-151,154-181,184-188,191-195,198-202,205,208,212-216,220,221 and 224.

Continuation of Disposition of Claims: Claims rejected are 1,5-14,84,97,98,100,101,103-107,128,130-132,134-137,139-141,148,152,153,182,183,189,190,196,197,203,204,206,207,209-211,217 and 218.

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This Office action is in response to Applicants' remarks received October 24, 2008.

Applicants' arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn.

Claims 2-3, 19-83, 85-96, 99, 109, 118, 129, 133, 138, 142, 219, 222-223, 225 are canceled. Claims 4, 15-18, 102, 108, 110-117, 119-127, 143-147, 149-151, 154-181, 184-188, 191-195, 198-202, 205, 208, 212-216, 220-221, 224 are withdrawn. Claims 1, 5-14, 84, 97-98, 100-101, 103-107, 128, 130-132, 134-137, 139-141, 148, 152-153, 182-183, 189-190, 196-197, 203-204, 206-207, 209-211, 217-218 are currently under examination.

Priority: The request for benefit to provisional application 60/432317, filed December 9, 2002, is acknowledged.

Objections and Rejections

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-14, 84, 97-98, 100-101, 103-107, 128, 130-132, 134-137, 139-141, 148, 152-153, 182-183, 189-190, 196-197, 203-204, 206-207, 209-211, 217-218 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desai et al. (WO 0071079; IDS 02.23.07) in view of

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Gelfand et al. (EP 0227593; IDS 12,20.04) and further in view of Flournoy (1991 Eur J Clin Microbiol Infect Dis 10(7): 597-598; IDS 06.13.07).

The instant claims are essentially drawn to a pharmaceutical composition comprising human serum albumin (pharmaceutical carrier), deferoxamine, and a pharmaceutical agent (paclitaxel). The deferoxamine is present in an amount effective to inhibit microbial growth and the weight ratio of human serum albumin to pharmaceutical agent is about 1:1 to about 18:1.

Desai et al. disclose a composition comprising a water insoluble pharmacological agent (i.e., paclitaxel) and a carrier protein (i.e., human serum albumin) (p. 8 lines 9-24). Desai et al. further disclose that said composition can be sterile and can be formed into nanoparticles of less than or equal to 200 nm, and that the ratio of albumin to pharmaceutical agent can be about 13:1 (p. 8 lines 25-28, p. 46 example 6). Desai et al. also disclose that the nanoparticles may be lyophilized and may be resuspended in an aqueous solution to the original dispersion (p. 46 example 6). Desai et al. disclose that the paclitaxel is free of cremophor (p. 8 lines 13-14). Desai et al. further disclose that said compositions can comprise antimicrobials as the pharmaceutical agent (p. 28), as well as suggest that more than one pharmacological agent(s) can be combined together to form said composition (p. 108 lines 5-8). Desai et al. do not explicitly teach that said composition comprises both paclitaxel and an antimicrobial agent.

Gelfand et al. disclose that iron chelating agents, particularly deferoxamine, in connection with the synergistic treatment of cancer, can be prepared in combination with cancer drugs (abstract, p. 3). Gelfand et al. do not teach deferoxamine has antimicrobial properties.

Flournoy discloses that deferoxamine mesylate (DFM) is an iron chelator with antimicrobial properties (p. 597).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Desai et al. by further incorporating the deferoxamine of Gelfand et al. and Fluornoy into the human serum albumin:paclitaxel composition of Desai et al. (claims 1, 5-14, 84, 97-98, 100-101, 103-107, 128, 130-132, 134-137, 139-141, 148, 152-153, 182-183, 189-190, 196-197, 203-204, 206-207, 209-211, 217-218). The motivation to do so is given by Desai et al., which suggest that pharmacological active agents (i.e. antineoplastics, antimicrobials) can be combined into a composition with an albumin protein carrier and Gelfand et al. and Fluornoy et al., which disclose that deferoxamine is an iron chelator that has a synergistic effect when used with antineoplastic drugs, as well as antimicrobial properties that one of ordinary skill would recognize to be beneficial in preventing the growth of microorganisms in said composition. Regarding the effective amount of deferoxamine, it would have been a matter of routine experimentation for one of ordinary skill to administer said deferoxamine at a dosage that would not cause a toxicological effect in a patient.

Applicants' amendments and remarks are persuasive to overcome the previous art rejections under 35 U.S.C. 102(b) and 103(a). The previous rejections under 35 U.S.C. 102(b) and 103(a) have been withdrawn. However, the instant claims are believed to be unpatentable in view of the new 103(a) rejections as noted above.

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is (571)272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 30, 2008

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657